UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

JUDY WETHINGTON, et al.,	:	**Case No. C-1-01-441**
	:	
Plaintiffs,	:	**Judge Spiegel**
	:	
vs.	:	
	:	
PURDUE PHARMA, L. P., et al.,	:	
	:	
Defendants.	:	

PLAINTIFF WETHINGTON'S REPLY MEMORNADUM IN SUPPORT OF MOTION TO RECONSIDER ORDER DENYING CLASS CERTIFICATION

INTRODUCTION

Plaintiffs seek reconsideration of this Court's denial of class certification. Based on recently obtained evidence, Plaintiffs are convinced that class certification will simplify the litigation. Indeed, the new evidence reveals that class certification will resolve in a single adjudication whether OxyContin® is a defective product.

The recent evidence consists of a United States Drug Enforcement Administration ("DEA") Report. In the Report, the DEA, for the first time, expressly stated that OxyContin® is highly addictive. The DEA's pronouncement

directly contradicts Defendants' representations that OxyContin® rarely causes addiction.

In addition to the DEA Report a recently filed whistle blower action in Connecticut establishes the existence of a predominant common issue concerning Defendants' manufacture, promotion and distribution of OxyContin®. Based on the revelations in the Connecticut lawsuit, Plaintiffs have discovered that OxyContin® is appreciably more addictive than an ordinary physician would expect when prescribing OxyContin®.

Defendants attempt to minimize the impact of these developments by claiming that the product defects do not affect members of the class. Defendants wrongly assert that Plaintiffs are not seeking to represent drug abusers. Purdue Defendants' Opposition to Reconsideration at 6. This representation is in error. Plaintiffs, in fact, are seeking to represent all people who first received OxyContin® pursuant to a lawful prescription. The recent revelations reveal that the defective characteristics of OxyContin® proximately caused the abuse and addiction.

BACKGOUND

The United States Drug Administration ("DEA") in its October 2003 Report expressly states that OxyContin® is "highly addictive". This statement is the first public recognition that OxyContin® is highly addictive and easy to abuse. Indeed,

early package inserts used by Defendants touted the following: "Delayed absorption, as provided by OxyContin tables, is believed to reduce the abuse liability of the drug." ***See*** Package Inserts attached to Purdue Defendants' Opposition to Plaintiff's Motion for Class Certification. In light of the DEA's new and recent confirmation that OxyContin® is highly addictive and easily abused, Defendants' clearly misrepresented the dangers of OxyContin® to the medical community.

New evidence also establishes that the OxyContin®'s important characteristic of "delayed absorption" may be in error. Plaintiffs' previously attached the complaint of Marek Zakrzewski, PhD a former assistant Director at Defendant Purdue and a Purdue researcher. In the complaint, Dr. Zakrzewski described how and why OxyContin® is defective and likely to lead to addiction and abuse.

After the Court issued its October 1, 2003, Order denying class certification, Dr. Zakrzewski filed an amended complaint. The Amended Complaint provides in greater detail the defects inherent in OxyContin®. A copy of the Complaint is attached as Exhibit "A". According to Dr. Zakrzewski, in his amended complaint, Defendants purposely hid from the United States Food and Drug Administration ("FDA") and the medical community that OxyContin was defective because of inconsistent rates of absorption.

15. Defendants have claimed in its advertisements of OxyContin that OxyContin can provide controlled delivery of the parent drug Oxycodone HCl over a 12 hour period.

16. The molecular structure of Oxycodone HCl effects the time it takes for the drug to cross the blood-brain barrier. This time to onset of effects is a critical factor in the addictive potential of a drug, as a substance which gives a quick and immediate high is more addictive to the brain than one which comes on gradually.

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22. In May, 2001, Plaintiff discovered that polymorphic forms of Oxycodone HCl were being supplied to Defendants and Defendants were utilizing these forms in the production of OxyContin. Plaintiff discovered that the polymorphic forms of Oxycodone HCl forms dissolved at differing rates of speed. Additionally, he discovered that the polymorphic forms of Oxycodone HCl were unstable and when exposed to increased humidity or the passage of time would continue to transmute into other polymorphic forms of Oxycodone HCl.

23. These polymorphs differed structurally from the form of Oxycodone HCl originally approved by the FDA for use in Defendants' NDA. The discovery of polymorphic forms of Oxycodone HCl constituted a "major change" pursuant to FDA guidelines. Accordingly, and pursuant to 21 C.F.R. § 314.70, Defendants were required to immediately notify the FDA.

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25. These polymorphic forms of Oxycodone HCl with variable dissolution speeds were used by Defendants in uncontrolled amounts in the production of OxyContin.

26. The use of a faster dissolving form of Oxycodone HCl from that which was approved by the FDA could dissolve more quickly into the human body than expected and cause overdosing and potentially lead to addiction. Alternatively, a slower dissolving form of Oxycodone HCl would not provide a patient with the anticipated pain relief. This could lead a patient to consume

> **additional OxyContin and contribute to over dosage.** (emphasis added)

This new information was unavailable when the Court heard argument. More importantly, the new evidence establishes that Defendants kept this information from FDA and never informed doctors that the varying rates of dissolution could cause addiction and encourage abuse. The new evidence, therefore, demonstrates that the purported benefits of OxyContin® may be illusory.

ARGUMENT

I. The Court should reconsider its denial of Class Certification

A. Plaintiffs timely filed their request for reconsideration

The fundamental objection to Plaintiffs' motion is the claim that Plaintiffs filed the motion too late. Defendants, however, failed to recognize that class certification orders are conditional and always are subject to review. Indeed, the Untied States District Court for the Northern District of Mississippi rejected the argument in ***Anderson v. Douglas & Lomason Company***, 122 F.R.D. 502 (N.D. Miss. 1988). According to the ***Anderson*** Court,

> [t]here is not provision in the Federal Rules of Civil Procedure for a motion to reconsider an interlocutory order[1]…Motions for reconsideration of orders making final disposition of a previous motion are generally traded…as Rule 59 or 60 motions. However, **the motion to certify a class under Rule 23 is a different sort of creature**. Rule 23(c)(1) clearly provides that an order certifying or

[1] ***See*** Purdue's opposition at p. 7, note 3, (federal rules do not discuss motion to reconsider class certification orders)

> refusing to certify a class remains open to amendment or modification throughout the course of the trial. (emphasis added)

Id. at 504. After providing this reasoning, the trial court reviewed its previous denial of class certification and certified several subclasses. **Id**. at 507.

Although Defendants' objection, based merely on Civil Rule 23 (c)(1), is without merit, Defendants objection also is in error because it ignores Civil Rule 60. Civil Rule 60 (b) (2) permits parties to seek further review of an Order of the Court if the party discovers new evidence. Here, Plaintiffs correctly have asserted that they have discovered new evidence. In fact, the Defendant Purdue provides proof that the evidence is new by submitting a counter affidavit of Glenn Van Buskerk. If the evidence already had been before the Court, Defendants simply could have referred to previous submissions.

B. The new evidence creates a predominant common issue regarding whether Defendants manufactured, promoted, sold, and distributed a defective product

In its opposition, the Purdue Defendant asserts that it "has always conducted the tests required by FDA to ensure that the medication continues to meet all safety requirements, and always makes the necessary disclosures to FDA." Purdue Opposition at 5. Obviously, this was an important "fact" that helped to sway the trial court that it should deny class certification.

The new evidence demonstrates that predominate issues of fact exist regarding FDA disclosures and Defendants' compliance with safety requirements.

In his recently filed amended complaint, Dr. Zakrzewski provides a detailed discussion of why Purdue's representations regarding safety, testing and FDA disclosure are false. Dr. Zakrzewski, for example, describes how Defendants sought to avoid FDA scrutiny of the rate that OxyContin® dissolved.

> 30. Following Plaintiff's discovery that polymorphic forms of OxyCodone HCl existed and were being utilized in the manufacture of OxyContin, Philip Goliber, Plaintiff's immediate superior, told Plaintiff that he was forbidden from producing any record of testing the dissolution properties of different forms of Oxycodone HCl.
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> 31. During this time, Purdue was being sued by users of OxyContin who had overdosed on and/or had become addicted to the drug. Plaintiff stated to his superiors that the tablets of OxyContin that were being made with the faster dissolving form of Oxycodone HCl may be causing overdoses and could lead to addiction. Plaintiff was ordered by Goliber to never talk about his concerns again.
>
> 32. Plaintiff protested management's decision to forbid further testing and told his superiors that the FDA should be notified of the existence of the different forms of Oxycodone HCl. Indeed, Plaintiff specifically told management that FDA regulations required that the polymorphs that he discovered be tested and reported to the FDA in accordance with FDA requirements governing supplements and other changes to an approved application (21 C.F.R. § 314.70) and industry guidance issued by the FDA which appears at 65 Fed. Reg. 83046.
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> 33. Plaintiff presented management with a copy of 65 Fed. Reg. 83046 which set forth the testing steps needed to be taken when polymorphisms are discovered. Plaintiff discussed these requirements at said monthly meetings.
>
> 34. Management forbade Plaintiff from continuing with the testing steps set forth in the 65 Fed Reg. 83046.

See Dr. Zakrzewski attached as Exhibit "A".

Dr. Zakrzewski further provides a detailed explanation regarding Defendants' efforts to avoid FDA review of problems associated with the manner that Defendants measured the size of particles and the effect that the measurement standards had on the rate of dissolution.

> 39. Plaintiff developed a new method to measure particle size and proposed new tighter particle size specifications as requested by the FDA.
>
> 40. Plaintiff proposed testing the different forms of Oxycodone HCl that Defendants were using in the production of OxyContin by producing tablets of OxyContin with the different forms which dissolved at different rates of speed. Then Defendants could determine whether or not some tablets of OxyContin could dissolve faster than others depending on which form of Oxycodone HCl was present in a particular tablet.
>
> 41. Goliber told Plaintiff that he was not allowed to perform said tests and Defendants would not adopt tighter particle size specifications. Further, Goliber ultimately also forbade Plaintiff from communicating with the regulatory department within the company regarding his findings and forbade him from including in any written report his findings regarding the effect of different particle sizes on dissolution rates and the dissolution rates of the different forms of Oxycodone HCl.
>
> 42. Goliber told Plaintiff that Defendants did not want any record of testing done on Oxycodone HCl. This directive was issued in order to avoid the creation of documentation which could be subpoenaed or would need to be turned over to the FDA.
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> 43. Defendants did not inform the FDA that the method for measuring particle size identified in the NDA was less accurate than other methods and that it had developed a more accurate particle size testing procedure.

See Dr. Zakrzewski attached as Exhibit "A".

This information that Defendants failed to share with Plaintiffs during class discovery is material. The Zakrzewski complaint is supported by the DEA's new announcement that OxyContin® is highly addictive and easily abused. Clearly, if the high incidence of addiction is proximately caused by a previously unknown and undisclosed manufacturing defect, class certification is appropriate. ***In re Copley Pharmaceutical, Inc.***, 158 F.R.D. 485 (D. Wyo 1994).

The ease of abuse previously unrecognized by the DEA and denied by Defendants is significant and supports a renewed examination. The parties now are aware that Purdue made a material misrepresentation in its package insert. When it introduced OxyContin®, Purdue included in its early package inserts the bold statement that "**Delayed absorption**, as provided by OxyContin tables, **is believed to reduce the abuse liability** of the drug." (emphasis added) ***See*** Package Inserts attached to Purdue Defendants' Opposition to Plaintiff's Motion for Class Certification. This important statement to the medical community regarding absorption is wrong. Indeed, the October 2003 DEA Report directly contradicts this representation. According to the DEA, the current formulation of OxyContin® was flawed and that Purdue and Abbott should reformulate OxyContin® to reduce abuse of the product, particularly by injection. DEA Report at 8, attached to Plaintiff Wethington's Motion for Reconsideration.

Additionally, Purdue opposed class certification on the mistaken premise that the Plaintiff Class excluded any user of OxyContin® who abused the medication. Purdue Opposition to reconsider class certification at 6. The proposed class, however, includes any person in Ohio, West Virginia, Kentucky, and Indiana who lawfully obtained OxyContin® in the first instance. The new evidence demonstrates that OxyContin® is substantially more addictive and dangerous than a prescribing physician would expect. The reason that it is more dangerous is because the manufacturing process is providing OxyContin® with variable rates of dissolution. These fluctuations make the medication significantly more susceptible to abuse and addiction than is represented in the package insert and than was reported to FDA. Thus, people who became addicted and/or abused OxyContin® **after receiving a physician's prescription** are entitled to pursue a claim.

C. The new evidence supports holding the class certification order in abeyance

By submitting a counter affidavit, Defendant has acknowledged, at a minimum, a difference of opinion regarding the substance of Dr. Zakrzewski's allegations. Although Plaintiffs are confident that the new information supports reconsideration, the Court, at a minimum, should permit the parties to explore these new facts before affirmatively ruling that class certification is inappropriate. Indeed, under "Rule 23, the district court is charged with the duty of monitoring its

class decisions in light of the evidentiary development of the case." ***Richardson v. Byrd***, 709 F.2d 1016, 1019 (5th Cir. 1983).

The Court consistent with its authority under Rule 16 and Rule 23 can hold its order in abeyance. If the Court chooses this option, Plaintiffs request an immediate scheduling conference to permit the parties to set a schedule to consider the effects of the newly obtained evidence and to set a hearing.

CONCLUSION

For the reasons contained in this Memorandum, the Court should withdraw its Order denying class certification and reconsider its denial of class certification.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that a copy of Plaintiff Wethington's Reply Memorandum in support of Motion for Reconsideration was served by regular United States mail; postage prepaid and by Electronic Service on the following counsel for Defendants this ***17*th** day of December 2003:

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